Serial No.: 10/535,383 Filed: May 16, 2005

Ý,

٠,

Office Action Mailing Date: October 30, 2007

Examiner: Rajarshi GANGULY

Group Art Unit: 4153 Attorney Docket: 37443

REMARKS

The present application includes claims 1, 3, 4, 18, 19, 21, 25, 26, 29-36, 41, 43, 51, 77, and 82-85. The claims have been amended so as to correct various technical errors appearing therein, as will be discussed below. Claim 1 has also been amended, and new claim 86 has been added. It is submitted that no new matter has been added to the claims, and that support for the amendment to claim 1 and for new claim 86 may be found, for example, at page 13, line 13, and at page 25, line 1, of the present application, respectively.

The present application now comprises, after amendments, 1, 3, 4, 18, 19, 21, 25, 26, 29-36, 41, 43, 51, 77, and 82-86, of which claims 1, 31, and 77 are in independent form.

Reconsideration of the above-identified application in view of the new and amended claims and the following remarks is respectfully requested.

Drawings

The Examiner has objected to Figure 11C, as it does not clearly show "a plurality of nozzles that are each fed by a separate tube." On consideration of this objection, Applicants are submitting herewith a new Drawing Sheet 19/25, wherein Figure 11C has been amended to more clearly illustrate the structural details of the nozzle design. It is submitted that support for the amendment to Figure 11C may be found, for example, at page 23, line 27, which states that "Fig. 11C shows a nozzle set 1120, in which a plurality of nozzles 1124 are each fed by a separate tube (not shown)."

Specification and Claim Objections

The Examiner has objected to the specification and abstract of the application due to various spelling and grammatical errors. The Examiner has also objected to the claims as containing various technical errors. On consideration of this objection, Applicants have amended the specification, claims, and abstract of the application accordingly, and has further amended the abstract so as to correspond to the amended claims. It is submitted that these amendments are purely cosmetic, and do not change the scope of the application. As to claims 25 and 26 indicated by the Examiner, it is submitted that each of these correctly recites "said removing" and thus requires no correction as to this wording.

Serial No.: 10/535,383 Filed: May 16, 2005

¥

1)

÷,

Office Action Mailing Date: October 30, 2007

Examiner: Rajarshi GANGULY

Group Art Unit: 4153 Attorney Docket: 37443

Claim Rejections - 35 U.S.C. §112

In this section of the Office Action, claim 26 (dependent on claim 1) was rejected as reciting a method which conflicts with claim 1. On consideration of this rejection, Applicants have amended claim 26 in a manner it is believed will more distinctly recite the subject matter of the invention, so as not to conflict with claim 1. It is submitted that this amendment does not change the scope of the claim and that the phrase "said adhesive is sufficiently set" in this claim is intended to mean that the adhesive has started to set.

Claim Rejections - 35 U.S.C. §102

In this section of the Office Action, claims 1, 3, 4, 18, 19, 29, 30, 31, 33-35, 43, 82, and 83 were rejected under 35 U.S.C. §102(b) as being anticipated by Popov et al. (US Patent No. 6,068,637). In response, claim 1 has been amended so as to more clearly distinguish between the claimed invention and the device to Popov et al. It is submitted that claims 1, 3, 4, 18, 19, 29, 30, 31, 33-35, 43, 82, and 83 are patentable, in the light of arguments set forth below.

It is submitted that there is no prima facie basis for the Examiner's assertion that these claims are anticipated by the teachings of Popov et al, as will be discussed below.

Popov et al. teach devices for performing anastomosis between the end of a LIMA (left internal mammary artery) and the side of an LAD (left anterior descending coronary artery). A cutter catheter is <u>inserted inside the end of the LIMA</u>. A corkscrew element pierces the side wall of the LAD, thus positioning the LIMA relative to the LAD. The LIMA and LAD are anastomosed by means of clips applied by clip appliers (46 and 48) or (50 and 52), or sutures. Alternatively, the anastomosis may be achieved by a suitable adherent (column 10, line 63). A cutter then cuts a circular portion out of the side of the LAD. Finally, the cutter, corkscrew element, and circular cutout portion are removed via the LIMA.

Popov et al. thus teach away from the present invention as recited in amended claim 1, the method comprising "juxtaposing first and second blood vessels to be anastomosed using a juxtaposition device, to a desired configuration in which at least <u>said first vessel is an end vessel</u>," "wherein said juxtaposition device remains primarily <u>external to at least said first vessel</u> during the juxtaposing."

Additionally, Popov et al. teach away from the present invention as recited in claim 31, which comprises "attaching at least a first external scaffold element to a first blood vessel" and

Serial No.: 10/535,383 Filed: May 16, 2005

¥.__

7

Office Action Mailing Date: October 30, 2007

Examiner: Rajarshi GANGULY

Group Art Unit: 4153 Attorney Docket: 37443

"attaching at least said first <u>external</u> scaffold element or a second <u>external</u> scaffold element to a second blood vessel."

As to the elements 70 and 72 to Popov et al. indicated by the Examiner (paragraph 10 of the Office Action), these are <u>glue appliers</u> and not a <u>juxtaposition device</u> (claim 1) or <u>scaffolding elements</u> for "positioning said blood vessels" (claim 31), as suggested in the Office Action. The only means taught by Popov et al. for positioning the LIMA next to the LAD is "endoscopic assistance" (column 7, line 46), for which no details are provided.

In light of the above, it is submitted that independent claims 1 (now amended), 31, and 77 are not anticipated by Popov et al. and are, therefore, allowable. It is further submitted that claims (3, 4, 18, 19, 29, 30, and 82-83) and (33-35, and 43) are allowable, as they depend from allowable claims 1 and 31, respectively.

Claim Rejections - 35 U.S.C. §103

In paragraph 23 of the Office Action, claims 25 and 26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Popov et al. in view of Detweiler (US Patent No. 5,141,516). Applicants respectfully traverse this rejection.

Neither of the cited references teaches the limitations found in amended independent claim 1, namely those of "juxtaposing first and second blood vessels to be anastomosed using a juxtaposition device, to a desired configuration in which at least said first vessel is an end vessel" and "wherein said juxtaposition device remains primarily <u>external</u> to at least said first vessel during the juxtaposing." It is submitted that, since these limitations found in the independent claim 1, from which claims 25 and 26 depend, are not taught by the cited art, claims 25 and 26 are patentable.

As noted above, Popov et al. teach away from the claimed invention recited in claim 1.

Detweiler teaches a dissolvable anastomosis stent 10 comprising engageable male and female members to be <u>inserted into first and second vessel stumps</u>. Detweiler thus teaches away from the present invention as recited in Claim 1, "wherein said juxtaposition device remains primarily <u>external</u> to at least said first vessel during the juxtaposing."

Additionally, one would not be inclined to combine Popov et al. with Detweiler, since Popov et al. teach a device for anastomosis of an <u>open ended blood vessel</u> with the <u>intact side</u> wall of another blood vessel (not an end vessel), while Detweiler teaches anastomosis of <u>two</u>

Serial No.: 10/535,383 Filed: May 16, 2005

.

1

٠, ا

Office Action Mailing Date: October 30, 2007

Examiner: Rajarshi GANGULY

Group Art Unit: 4153 Attorney Docket: 37443

<u>open-ended blood vessels</u> into which the male and female members of the device must be introduced. It is not clear if, nor how, the teachings would be combined.

In view of the foregoing discussion, it is submitted that amended claim 1 is patentable over Popov et al. in view of Detweiler. It is further submitted that claims 25 and 26 are patentable as they depend from allowable amended independent claim 1.

In paragraph 24 of the Office Action, claim 32 was rejected under 35 U.S.C. §103(a) as being unpatentable over Popov et al. in view of Schenck (US Patent No. 4,553,542). Applicants respectfully traverse this rejection.

Neither of the cited references teaches the limitations found in independent claim 31, namely those of "attaching at least a first external scaffold element to a first blood vessel; attaching at least said first external scaffold element or a second external scaffold element to a second blood vessel" and "positioning said blood vessels using said at least a first external scaffold element, to a desired configuration." It is submitted that, since these limitations found in the independent claim 31, from which claim 32 depends, are not taught by the cited art, claim 32 is patentable.

As noted above, Popov et al. teach away from the present invention recited in claim 31. Also as noted above, elements 70 and 72 (Figs. 10-11 of the patent to Popov et al.) indicated by the Examiner are glue appliers, not scaffolding elements as in the present invention for "positioning said blood vessels using said at least a first external scaffold element, to a desired configuration" (claim 31).

Schenck et al. teach a circular device to which the open ends of blood vessels are tethered by means of hooks or sutures at at least three points. The ends of the blood vessels are thus stretched, which also everts the end portions and holds them tightly against each other, so that a seal is formed therebetween (column 6, line 15). The ring may alternatively be of any polygonal shape, such as triangular or square (column 6, line 50). The ring is to be <u>implanted in the body</u>, at least until the anastomosis is healed (column 7, line 26). Schenck et al. do not teach "removing said at least first external scaffolding element" as recited in claim 31.

Also, one would not be inclined, nor would it be clear how to combine the device to Popov et al. with the device to Schenck et al., since Popov et al. teach a device for anastomosis of an open ended blood vessel with the <u>intact side wall</u> of another blood vessel, while Schenck et al. teach anastomosis of two blood vessels having openings therein.

Serial No.: 10/535,383 Filed: May 16, 2005

ř.,

•

Office Action Mailing Date: October 30, 2007

Examiner: Rajarshi GANGULY

Group Art Unit: 4153 Attorney Docket: 37443

In view of the foregoing discussion, it is submitted that claim 31 is patentable over Popov et al. in view of Schenck et al. It is further submitted that claim 32 is patentable as it depends from allowable independent claim 31.

In paragraph 25 of the Office Action, claim 51 was rejected under 35 U.S.C. §103(a) as being unpatentable over Popov et al. in view of Black et al (US Patent No. 6,245,083). Applicants respectfully traverse this rejection.

Neither of the cited references teaches the limitations found in independent claim 31, namely those of "attaching at least a first <u>external</u> scaffold element to a first blood vessel; attaching at least said first <u>external</u> scaffold element or a second <u>external</u> scaffold element to a second blood vessel" and "positioning said blood vessels using said at least a first <u>external</u> scaffold element, to a desired configuration." It is submitted that, since these limitations found in the independent claim 31, from which claim 51 depends, are not taught by the cited art, claim 51 is patentable.

As noted above, Popov et al. teach away from the present invention recited in claim 31.

Black et al. teach a technique for anastomosis whereby a needle is inserted into two adjacent blood vessels in order to create an aperture in the wall of the blood vessels. A balloon device is pushed through both apertures such that a pair of balloons is inflated within the blood vessels to secure the blood vessels in place alongside each other (fig. 4d). A bioadhesive is then applied (column 6, line 22). Contrary to the claimed invention, Black et al do not teach the use of external scaffold elements, as recited in Claim 31.

Also, one would not be inclined, nor would it be clear how to combine the device of Popov et al. with the device of Black et al., since Popov et al. teach a device for anastomosis of an <u>open ended blood vessel</u> with the <u>intact side wall</u> of another blood vessel, while Black et al. teach anastomosis of two adjacent intact blood vessels.

In view of the foregoing discussion, it is submitted that claim 31 is patentable over Popov et al. in view of Schenck et al. It is further submitted that claim 32 is patentable as it depends from allowable independent claim 31.

In paragraph 26 of the Office Action, claims 1, 3, and 4 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sancoff et al. (US Patent No. 6,682,540) in view of Bessler et al. (US Patent No. 5,411,508). Applicants respectfully traverse this rejection.

Serial No.: 10/535,383 Filed: May 16, 2005

٠.

·ų

Office Action Mailing Date: October 30, 2007

Examiner: Rajarshi GANGULY

Group Art Unit: 4153 Attorney Docket: 37443

Neither of the cited references teaches the limitations found in amended independent Claim 1, namely "removing said juxtaposition device after said adhesive sufficiently sets"; "wherein said juxtaposition device remains primarily external to at least said first vessel during the juxtaposing." It is submitted that, since these limitations, which are found in amended independent claim 1, are not found in either of the cited references, amended independent claim 1 is patentable thereover. It is further submitted that, since these limitations found in amended independent claim 1, from which claims 3 and 4 depend, are not taught by the cited art, claims 3 and 4 are patentable.

Sancoff et al. teach a device for surgical formation of an anastomosis between two blood vessels. The device includes a crown 15 with a plurality of strands 20 joined together by at least two rings 25. Each strand has a pointed barb 35 at the end of the crown and a retaining ring 50 restrains the hooks, thus allowing positioning of the end of the crown. Removal of the retaining ring causes deployment of the hooks which secure the crown to a second blood vessel. The crown is first positioned over the end of a first blood vessel 55 and a scope is positioned within the first blood vessel (fig. 3). The end of the first blood vessel is folded back and impaled upon the hooks, after which the crown is positioned within a second vessel 65. The retaining ring is removed, releasing the hooks, which are driven through the second blood vessel. The gap between the edges of the blood vessels may be sealed by a sealing ring 70 and/or sutures 80, or a sealant (column 5, line 14). An optional clover leaf bender 82 turns the hooks toward the second blood vessel. In an alternative embodiment, the crown may be disposed within the first blood vessel, the crown secured inside the blood vessel by a lock ring 85. In all of the above embodiments to Sancoff et al., the crown remains within the body after the anastomosis has been performed.

Sancoff et al. also teach a further embodiment wherein <u>mandrel section 140 is inserted into the first blood vessel</u> 55 and a main body section 150 is placed over the first blood vessel 55, such that the flanged ends of sections 140 and 150 mate (column 5, line 34). A sleeve 175 is slidable along the outside of the main body section. By sliding the sleeve toward the flanged end, a series of wires 170 are pushed through the first vessel 55. When the tips of the wires reach the flanged end 145 of flexible mandrel 140, a die surface 195 deflects the wires outward and backward, such that they pierce the inner wall of the second blood vessel and go out of the wall of the second vessel as the sleeve is further advanced. Afterwards, the sections 140 and 150 may be removed.

Serial No.: 10/535,383 Filed: May 16, 2005

٨.,

•

ė,

Office Action Mailing Date: October 30, 2007

Examiner: Rajarshi GANGULY

Group Art Unit: 4153 Attorney Docket: 37443

The Examiner has suggested that Sancoff et al. discloses a method of performing an anastomosis including "removing said juxtaposition device after said adhesive sufficiently sets; wherein the juxtaposition device remains primarily external to at least one of the vessels during the juxtaposing." While figs. 1a-4n, 9-11, and 20 of the patent to Sancoff et al. may show a device which remains primarily external to the first blood vessel 55, this device is not removed after the anastomosis is performed. Instead, the device remains inside the body. As to the device shown in figs. 5a-c, this crown is positioned primarily internal to the first blood vessel 55 and is inserted into the second blood vessel 65. There is no means shown for removing the crown after the anastomosis procedure is completed. Similarly, the crown shown in figs. 14a-14b is primarily internal to both the first and second blood vessels and no means is taught for removing the crown. In contrast, amended claim 1 recites a method including "removing said juxtaposition device after said adhesive sufficiently sets."

The only embodiment taught by Sancoff et al. wherein the device is removed after the anastomosis is carried out is shown in figs. 21a-22f and 23a-25b. However, this embodiment includes a main body section 150 which is placed over the first blood vessel and a flexible mandrel 140 which is <u>inserted into the first blood vessel</u> (column 5, line 28). Thus, this embodiment of the device to Sancoff et al. is <u>not "external</u> to at least said first vessel" as recited in amended claim 1.

Bessler et al. teach a tissue attaching device wherein a stapling head comprises a head assembly 50 and an anvil member 52. The head assembly has a circular assembly of staple drivers 80, for driving staples in a circular array corresponding to the anvil surface, and an annular cutting blade 83. The <u>anvil member is inserted inside a first colon portion</u>, the <u>head assembly is inserted inside a second colon portion</u>, and each colon end is sutured. The anvil member and the head assembly are pulled toward one another and the colon ends are stapled and the ends of the colon tissue are cut away, after which the device is removed from the colon.

In another embodiment (fig. 9), clamping portions are inserted into the colon portions, the clamping portions are drawn together, the colon ends are clamped together, and the clamping portions are released after the tissue has been approximated. Alternatively, the clamping portions may remain within the colon until the crushed ends of the colon tissue die, which allows the clamping portions to be sloughed. Alternatively, the device may be biofragmentable, such that it is broken down and passes out of the body over a period of time. In a further embodiment (figs. 10a-d), the device includes first and second members 408 and

Serial No.: 10/535,383 Filed: May 16, 2005

^_,

1

ŶŢ

Office Action Mailing Date: October 30, 2007

Examiner: Rajarshi GANGULY

Group Art Unit: 4153 Attorney Docket: 37443

410 which are inserted into first and second colon portions. A barb 416 of the second member impales the inner wall of the second colon portion and pulls it toward the first colon portion and inward. A glue or soldering agent may be used to coat the outer surface of the second colon portion. Then a barb 432 of the first member impales the inner wall of the first colon portion and pulls it toward the second colon portion and inward. The colon ends may then be sutured, glued, lased, electrocauterized, or joined by other means. The first and second member may then clamp the colon ends together, after which the first member may be removed. The second member remains inside the body unless it biodegrades, as noted above.

In contrast to the devices taught by Bessler et al., amended claim 1 recites a method "wherein said juxtaposition device remains primarily <u>external</u> to at least said first vessel during the juxtaposing."

Also, one would not be inclined to combine the teachings of Sancoff et al. with those of Bessler et al., since Sancoff et al. teach a device (shown in figs. 21a-22f and 23a-25b, discussed above) wherein at least one portion is <u>external</u> to one of the blood vessels, while the device to Bessler et al. includes portions, both of which are <u>internal</u> to the blood vessels. Additionally, the device to Bessler et al. cannot be used for blood vessels since, after the procedure has been done, portions of the device must be removed from the colon and/or portions of the colon are sloughed off and must be removed by the colon. Such a process in a blood vessel would probably lead to fatal clotting.

In view of the foregoing discussion, it is submitted that claim 1 is patentable over Sancoff et al. in view of Bessler et al. It is further submitted that claims 3 and 4 are patentable over Sancoff et al. in view of Bessler et al., as they depend from allowable independent claim 1.

In paragraph 27 of the Office Action, claim 18 was rejected under 35 U.S.C. §103(a) as being unpatentable over Sancoff et al. in view of Bessler et al. and Redl et al. (US Patent No. 4,631,055). Applicants respectfully traverse this rejection.

As noted above, Sancoff et al. do not teach a device which is <u>removed</u> after anastomosis and is "external to at least said first vessel" as recited in amended claim 1.

As noted above, none of the embodiments taught by Bessler et al. "remains primarily external to at least said first vessel during the juxtaposing," as recited in amended claim 1.

Serial No.: 10/535,383 Filed: May 16, 2005

A___

٠, ز

Office Action Mailing Date: October 30, 2007

Examiner: Rajarshi GANGULY

Group Art Unit: 4153 Attorney Docket: 37443

Redl et al. teach a <u>device for applying adhesive</u>. The device includes a pair of syringe bodies (1 and 2) inserted into a holding means 3. The conical ends (25 and 26) of the syringe bodies project into recesses of a connecting head 27 and are connected therewith. By pressing on actuating means 17, the contents of the syringes are mixed together at the site of application of the adhesive. Thus, Redl et al. does not provide the limitations missing in the devices to Sancoff et al. and Bessler et al., namely "removing said juxtaposition device after said adhesive sufficiently sets; wherein said juxtaposition device remains primarily external to at least said first vessel during the juxtaposing" as recited in amended claim 1.

In view of the foregoing discussion, it is submitted that independent claim 1 is patentable over Sancoff et al. in view of Bessler et al. and Redl et al. It is further submitted that claim 18 is patentable over Sancoff et al. in view of Bessler et al. and Redl et al., as it depends from allowable independent claim 1.

In paragraph 28 of the Office Action, claim 21 was rejected under 35 U.S.C. §103(a) as being unpatentable over Sancoff et al. in view of Bessler et al. and Buijsrogge et al. ("Sutureless Coronary Anastomosis with an Anastomotic Device and Tissue Adhesive in Off-Pump Porcine Coronary Bypass Grafting"). Applicants respectfully traverse this rejection.

As noted above, neither Sancoff et al. nor Bessler et al. teach "removing said juxtaposition device after said adhesive sufficiently sets; wherein said juxtaposition device remains primarily external to at least said first vessel during the juxtaposing" as recited in amended claim 1.

Buijsrogge et al. teach a technique for coronary anastomosis which provides an alternative to conventional suturing or mechanical coupling by utilizing extraluminal frame-based coupling and adhesive bonding at the site of the anastomosis. Buijsrogge et al. thus do not teach the limitations of claim 1.

In view of the foregoing discussion, it is submitted that amended independent claim 1 is patentable over Sancoff et al. in view of Bessler et al. and Buijsrogge et al. It is further submitted that claim 21 is patentable over Sancoff et al. in view of Bessler et al. and Buijsrogge et al., as it depends from allowable amended independent claim 1.

Serial No.: 10/535,383 Filed: May 16, 2005

•

ě. j

Office Action Mailing Date: October 30, 2007

Examiner: Rajarshi GANGULY

Group Art Unit: 4153 Attorney Docket: 37443

In paragraph 29 of the Office Action, claims 31, 33-35, and 41 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sancoff et al. in view of Bessler et al. Applicants respectfully traverse this rejection.

As noted above with regard to Sancoff et al. do not teach <u>external</u> scaffolding elements and "removing said at least first external scaffolding element," as recited in claim 31.

As noted above, Bessler et al. do not teach portions which are positioned <u>external</u> to the tissue portions to be joined, as recited in claim 31.

In view of the foregoing discussion, it is submitted that independent claim 31 is patentable over Sancoff et al. in view of Bessler et al. It is further submitted that each of claims 33-35 and 41 is patentable over Sancoff et al. in view of Bessler et al., as it depends from allowable independent claim 31.

In paragraph 30 of the Office Action, claim 36 was rejected under 35 U.S.C. §103(a) as being unpatentable over Sancoff et al. in view of Bessler et al. and Buijsrogge et al. Applicants respectfully traverse this rejection.

As noted above with regard to Sancoff et al. do not teach <u>external</u> scaffolding elements and "removing said at least first external scaffolding element," as recited in claim 31.

As noted above, Bessler et al. do not teach portions which are positioned <u>external</u> to the tissue portions to be joined, as recited in claim 31.

Buijsrogge et al. teach a technique for coronary anastomosis which provides an alternative to conventional suturing or mechanical coupling by utilizing extraluminal frame-based coupling and adhesive bonding at the site of the anastomosis. Buijsrogge et al. do not teach the limitations missing in Sancoff et al. and Bessler et al., namely "attaching at least a first external scaffold element to a first blood vessel; attaching at least said first external scaffold element or a second external scaffold element to a second blood vessel" and "removing said at least first external scaffolding element" as recited in claim 31.

In view of the foregoing discussion, it is submitted that independent claim 31 is patentable over Sancoff et al. in view of Bessler et al. and Buijsrogge et al. It is further submitted that claim 36 is patentable over Sancoff et al. in view of Bessler et al. and Buijsrogge et al., as it depends from allowable independent claim 31.

Serial No.: 10/535,383 Filed: May 16, 2005

4_

7

و ۹

Office Action Mailing Date: October 30, 2007

Examiner: Rajarshi GANGULY

Group Art Unit: 4153 Attorney Docket: 37443

In paragraph 31 of the Office Action, claims 77, 84, and 85 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nicholas et al. (US Patent Application Publication No. 2001/0029384) in view of Popov et al. Applicants respectfully traverse this rejection.

Neither of the cited references teaches the limitations found in independent claim 77, namely "An adhesive anastomotic system, comprising: a <u>first blood vessel holder</u>; a <u>second blood vessel holder adapted to interlock with said first blood vessel holder</u>, such that blood vessels held by said two vessel holders contact; and an adhesive port on at least one of said first vessel holder and said second vessel holder, said port configured to deliver an adhesive to said contact at an external portion of the contact."

Nicholas et al. teach an instrument for performing anastomosis without the need for manual suturing (paragraph 0083). The free end of an internal mammary artery (IMA) is inserted through a lateral opening 210 of disposable loading unit (DLU) 112 and is passed out a distal end opening. The free end of the IMA is then everted and retained by portions of clips 158 (paragraph 0085 and figs. 14-16). The DLU with the everted IMA is inserted into an incision in a left anterior descending artery (LAD) such that the walls of the LAD surrounding the incision are retained between the everted end of the IMA and the proximal ends of clips 158 (fig. 19). When actuated, the clips are deformed, clamping together the edges of the IMA and LAD (figs. 25-26 and paragraphs 0077 and 0087). Thereafter, the IMA is removed from the DLU (paragraph 0089).

Nicholas et al. do not teach "a second blood vessel holder adapted to interlock with said first blood vessel holder, such that blood vessels held by said two vessel holders contact," as recited in claim 77. Instead, Nicholas et al. teach utilizing the DLU (a first blood vessel holder) to hold the IMA (a first blood vessel) and to evert the end of the IMA, which is inserted into an incision in the LAD (the second blood vessel). There is no "second blood vessel holder" which interlocks with the DLU.

The Examiner has suggested that "Nicholas discloses a <u>first blood vessel holder</u> (116a), a <u>second blood vessel holder</u> (116b) adapted to interlock with said first blood vessel holder such that blood vessels held by said two vessel holders contact (figures 2-8)." It should, however, be noted that elements 116a and 116b are split half sections of device 100, which holds only <u>one</u> blood vessel (the IMA), as noted above. Nicholas et al. do not teach any second device for holding the second blood vessel (the LAD).

Serial No.: 10/535,383 Filed: May 16, 2005

و4

Office Action Mailing Date: October 30, 2007

Examiner: Rajarshi GANGULY

Group Art Unit: 4153 Attorney Docket: 37443

The Examiner has also suggested that "Nicholas also discloses a method wherein only one of said vessels is an end vessel and wherein the first blood vessel holder and the second blood vessel holder are each substantially outside their respective blood vessels (figures 14-17)." As noted above, there is no "second blood vessel holder" taught by Nicholas et al. Instead, the open-ended blood vessel is held by the DLU and portions of clips, and the edges of the two blood vessels are clamped together by bending of the clips.

As noted above, Popov et al. teach a device wherein "the pointed tip of the corkscrew element 30b pierces the sidewall 12a of the LAD 12 and the spiral body 30b is threaded through the sidewall 12 [sic] of the LAD 12 thereby further fixing the proximal severed end 10a in mating engagement with the proposed site for anastomosis 26 on the sidewall 12a of the LAD 12 (See FIG. 5)" (column 9, lines 59-64). The text states further that "the cutter catheter 14 will be sized and shaped to provide support to the LAD as the clips are applied" (column 10, line 53). Thus, it is clear from the text of this patent that the blood vessels are maintained in position by the corkscrew element 30b of the cutter catheter. Popov et al. do not teach "a first blood vessel holder" and "a second blood vessel holder adapted to interlock with said first blood vessel holder, such that blood vessels held by said two vessel holders contact," as recited in claim 77.

As noted above, it should be pointed out that figs. 10-11 of the patent to Popov et al. disclose glue appliers, not blood vessel holders as suggested by the Examiner. This is stated clearly in the text of the patent, specifically at column 10, line 66.

Further, one would not be inclined to combine the device of Nicholas et al., which holds the open-ended blood vessel externally, with the device of Popov et al., which is internal to the open-ended blood vessel.

In view of the foregoing discussion, it is submitted that claim 77 is patentable over Nicholas et al. in view of Popov et al. It is further submitted that claims 84 and 85 are patentable as they depend from allowable independent claim 77.

Serial No.: 10/535,383 Filed: May 16, 2005

j

Office Action Mailing Date: October 30, 2007

Examiner: Rajarshi GANGULY

Group Art Unit: 4153 Attorney Docket: 37443

All of the issues raised by the Examiner have been dealt with. In view of the foregoing, it is submitted that claims 1, 3, 4, 18, 19, 21, 25, 26, 29-36, 41, 43, 51, 77, and 82-85 pending in the application and new claim 86 are all in condition for allowance. An early Notice of Allowance is therefore respectfully requested.

Respectfully Submitted,

Martin O Moyniha

Martin D. Moynihan Registration No. 40,338

Date: April 28, 2008

Enclosures:

- Petition for Extension of Time (3 Months);
- Amendment Transmittal;
- Letter To Chief Draftsman;
- 1 Sheet of Annotated Marked-Up Drawing;
- Formal Drawing Transmittal Sheet; and
- 25 Sheets of Replacement Drawings

Serial No.: 10/535,383

ANNOTATED MARKED-UP SHEET

Sheet 1 of 1 Attorney Docket No.: 37443

Inventors: Amir LOSHAKOVE et al.

At

Title: ADHESIVE ANASTOMOSIS CONNECTION SYSTEM



19/25

-1100







